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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,201	12/19/2001	Mary K. Crow	5983/1H567US1	5071
7590 01/26/2004				
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			EXAMINER SAKELARIS, SALLY A	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,201	CROW, MARY K.	
	Examiner	Art Unit	
	Sally A Sakelarlis	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is written in response to applicant's correspondence submitted 11/4/2003. Claims 2 and 3 have been amended, claims 1 and 4-18 have been canceled, and claims 19-25 have been added. Claims 2, 3, and 19-25 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The present application's claim to benefit of a U.S. provisional Application 60/256,673 filed December 19, 2000, is granted.

Claim Objections

Claim 2 is objected to because of the following informalities: Claim 2 depends from claim 3. Appropriate correction is required to place claim 2 after the claim from which it depends.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 3, and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following: the breadth of the claims, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary. Claims 2, 3, and 19-25 are broadly drawn to a method of identifying any gene involved in Systemic lupus erythematosus(SLE) comprising identifying any region of the genome adjacent to a disease-associated marker, and selecting any gene in the region containing an L1 element in an intronic region or in a 5' or 3' regulatory region as a candidate gene involved in SLE. The specification does not at all enable identifying any gene involved in Systemic lupus erythematosus(SLE) comprising identifying any region of the genome adjacent to a disease-associated marker, and selecting any gene in the region containing an L1 element in an intronic region or in a 5' or 3' regulatory region as a candidate gene involved in SLE.

The specification teaches that LINEs(L1 elements) are believed to be fragments of a nucleotide sequence that has been distributed at many locations throughout the genome, and contain a 5' regulatory region and two open reading frames(ORF) that can encode two proteins (ORF1 and

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ORF2). These two ORFs are transcribed into mRNA, which are copied back (or parts of it) into DNA, and the DNA inserted back into the genome. Thus the specification teaches the key role of LINES in driving the increasing sophistication and diversity of the immune system throughout evolution to be supported by the heavy load of those elements in the segments of the genome encoding the MHC, immunoglobulin heavy and light chains, and T cell receptors. The specification also teaches that the presence of an L1 element within the regulatory region or in an intron of a gene can modify the expression of that gene and if that gene product is important in the immune or inflammatory pathways, altered expression of the gene product can contribute to autoimmune disease (Pg. 36). The specification teaches in Table 1 the chromosomal location of proposed SLE disease loci and full-length high fidelity L1 elements with the percent sequence identity being determined in comparison to nt 1-884 of accession no. U09116, a consensus sequence. The specification on page 11 also teaches that a "susceptibility locus" for a particular disease is a sequence or gene locus implicated in the initiation or progression of the disease. The specification additionally teaches that among the first and best studied germline insertions are those into factor VIII and dystrophin genes of individuals with sporadic hemophilia and muscular dystrophy. However, the specification has not established a clear correlation between any gene containing a full length L1 element in their intronic region or containing a full-length L1 element with high sequence fidelity to the L1 consensus sequence in their 5' or 3' regulatory region and all cases of SLE. Although a few examples are referenced, no teaching of similarities or commonalities of a shared characteristic between the L1 elements capable of conferring SLE exists. Furthermore the specification is silent to teachings of known markers of complex diseases. The specification provides no guidance on the effect had on the association between

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the marker and the L1 element as the distance between the two changes, which is to say, the specification has not asserted why a distance of zero Megabases between the L1 and marker results in the same correlating potential of another L1 and marker whose distance between the two is over 5M bp (Table 1 for example). It is further unpredictable then to practice the method wherein limitations of a distance between the first nucleotide of the L1 element and the first nucleotide of the gene is less than about 200,000 base pairs and 100,000 base pairs. The specification provides no guidance with respect to the significance of these distances as they have broadly claimed their method of identifying any gene involved in Systemic lupus erythematosus (SLE) comprising identifying any region of the genome adjacent to a disease-associated marker, and selecting any gene in the region containing an L1 element in an intronic region or in a 5' or 3' regulatory region as a candidate gene involved in SLE. Additionally, the specification omits any teachings in Table 1 of the why the listed markers are only "proposed SLE disease loci" (Table 1). There are no teachings in the specification regarding specific markers that have been associated with SLE in a clinical setting or otherwise. The specification further omits an explanation of how a L1 element with an 88% identity to consensus L1 is able to confer the same effect on a candidate gene that an L1 element with a 99% identity to a consensus L1 can. The specification does not teach the identification of any and all genes containing a L1 element as stated above that are necessarily associated with all cases of SLE.

As stated in *Vaek* (20 USPQ2d 1438), the specification must teach those of skill in the art how to make and how to use the invention as *broadly* as it is claimed" (emphasis added). The amount of guidance needed to enable the invention is related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher* 427 F. 2d 833, 839, 166

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USPQ 18, 24 (CCPA 1970). Predictability or lack thereof in the art refers to the ability of one of skill in the art to extrapolate the disclosed or known results to the invention that is claimed. If one of skill in the art can readily anticipate the effect of a change in the subject matter to which the claimed invention is directed, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change in the subject matter to which the claimed invention is directed, then there is unpredictability in the art. With respect to the present invention, one cannot readily anticipate a method of identifying any gene involved in SLE by identifying any region of the genome neighboring any SLE-associated marker, said method comprising identifying all genes containing a full length L1 element in their intronic region or containing a full-length L1 element with high sequence fidelity to the L1 consensus sequence in their 5' or 3' regulatory region, wherein all of these genes containing L1 elements as prescribed above are involved in every case of SLE from the art. More simply, one cannot anticipate that every gene containing a L1 element will be involved in SLE. In addition, the in the absence of specific guidance as to how to identify other markers associated with complex diseases and furthermore their response to a L1 insertion it would require undue experimentation to identify the additional genes that may be associated with all cases of SLE. Both the specification and art teach that much unpredictability exists concerning the practice of this broadly claimed method. The specification uses the results obtained with a small amount of independent, unrelated gene markers(Page 29 of Specification) and extrapolates them to all genes and all cases of SLE. Also the unpredictability in the state of the art is emphasized by the teachings in the Applicant's specification regarding the fact that "as the sequencing of the human genome is still in progress, precise locations and DNA sequences of genes and disease loci remain subject to revision

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pending completion of the full genome analysis in multiple individuals”. Which is to say that the existence of known, associated genetic markers is currently unpredictable. The specification also lends unpredictability to the claimed method in their assertion in Example 4, pg. 59 that “one of the chromosome 1q loci that has received the most attention and some strong support for linkage to SLE, containing the Fcγ receptor genes, did not show a nearby high fidelity L1 element(the calculated distance for FCGR2A was 4.78M bp)”(Pg. 59). The post-filing date art corroborates the unpredictability in the specification by teaching that much uncertainty exists in the potential for L1 integrations alone not even considering a correlation to specific complex diseases. Gilbert et al. teach that “little is known about how L1 integration is completed”(Cell, Vol. 110, 315-325, 2002). The reference points to further unpredictability in this claimed method through their teaching of “an unexpected outcome of our study ids that L1 retrotranspositions can result in a variety of target site alterations” and even more poignant to this claimed method’s unpredictablility the teaching that their “data provides strong experimental support for the hypothesis that L1 EN generates a sequence specific endonucleolytic nick in the bottom strand of the target sequence to initiate L1 retrotransposition”(Cell 322). This teaching concerning the unpredictable outcomes that result from L1 insertions makes the claim of being able to identify any and all genes associated with any all complex diseases to seem prophetic. Another piece of post-filing date art further substantiates the unpredictability present in this method of gene identification. Szak et al. teach that “the precise determination of the boundaries of L1 elements is complicated by the highly variable sequence and anatomy of L1 insertions.” “The most variable features of the L1s are the poly(a) tail, which has a variable length and can contain simple repeats...but many changes have also been reported in the coding regions of young L1s,

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especially in a segment of ORF1”(Genome Biology, Vol. 3, 2002). With respect to the present invention, one cannot readily anticipate any or all of the genes that may be involved in any or all complex diseases, by solely the identification of an L1 element as prescribed in the claims. Such random trial by error experimentation is considered to be undue and in view of the high level of unpredictability in the art and the lack of guidance provided in the specification, undue experimentation would be required for one of skill in the art to practice the invention as it is broadly claimed.

The specification provides no guidance as to how to predictably identify genes with L1 insertions that are reliably correlated with known markers of SLE. Furthermore, the specification fails to teach the known disease markers with which their L1 elements would be correlated. Lastly there was no connection between a specific (or set of) insertions that were consistently reproducible in their association to a certain known disease marker. The ability to establish this correlation is highly unpredictable and can only be determined through extensive, random, trial and error experimentation. Therefore, neither the specification nor the art provides the guidance necessary to how to predictably identify genes with L1 insertions that are reliably correlated with known markers of specific complex diseases. Thus, in light of the lack of breadth of the claims, the lack of guidance and working examples in the specification, the high level of unpredictability in the prior art and the quantity of experimentation necessary to practice the claimed invention, it is concluded that it would require undue experimentation to practice the claimed invention of claims 2, 3, and 19-25.

Response to Arguments:

On page 7 of applicants' response they assert that the Examiner appears to be of the opinion that for the invention to be enabled, every gene containing an L1 element must be involved in a complex disease. While the examiner acknowledges the amendment to the claim, applicant is reminded that such a teaching although not required, is just one way in which applicant could assert their method's enablement. Applicants further traverse the rejection by asserting that "the teachings of the Gilbert and Szak references mean nothing to the present invention"(Pg. 7 bottom). In response the examiner asserts that the art was cited to show the unpredictability that exists with respect to drawing such broad conclusions about the effects and definite associations involving L1 elements. The present invention's definition as being directed to a "simple test to identify candidate genes involved in SLE" is acknowledged however such a method is not considered simple for the above reasons set forth in the maintained rejection. With respect to applicant's arguments on the top of page 8 concerning the need for mechanistic information and the need for specific boundaries of the L1 element, again these are not required but are one way in which applicant could achieve enablement of their invention. Especially since much unpredictability exists in the specification such as that passage cited above in the rejection from page 59, Example 4. Furthermore, the specification on page 58 adds to the unpredictability by teaching that in "10 chromosome markers(that are to be assumed to be correlated with SLE) 6 were within 1.7cM of a *potentially* active L1 element and the 3 other loci... *may* be associated with SLE through a mechanism that does not involve L1 elements"(Pg. 58)...the specification omits the fate of the 10th marker. The specification is replete with such doubt-infused, putative speculation with respect to the "known" markers for SLE and the alleged L1 elements. So while the examiner acknowledges that the need for a mechanism is not necessarily required, in a case

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where other evidences of enablement are lacking, such a showing could help applicant achieve enablement. Furthermore, in response to applicant's argument regarding the examiner's assertion that there is no teaching as to similarities or commonalities between the L1 elements capable of conferring complex disease, the recited locations such as an intronic region or in a 5' or 3' regulatory region are enormous spaces within which many other factors could also reside that could account for the correlation. The examiner was trying to ascertain what properties of an L1 allowed it to be functional at varying similarities to the consensus as well as at varying distances from the marker genes. Lastly, in response to applicant's assertion that specific, SLE disease-associated markers are disclosed, while the examiner acknowledges that there are lists of "candidate genes", "proposed disease loci", and chromosomal locations, the examiner is not aware of a working example that featured the method as applied to an affected, or predisposed patient to SLE and the concurrent discovery of the associated marker and L1. While the cited art may in fact teach of the existence of markers well known in the art for SLE, the cited art is silent with respect to each of these known markers being associated with a L1 element of a certain % similarity located at a certain distance from the known marker. As a result the rejection is maintained.

***THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS***

35 U.S.C. 112, Written Description Rejection

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

The specification discloses SEQ ID NO: 1 which corresponds to the full-length human LINE-1(L1) element that is about 6000 bp in length with the Gen Bank Accession No. U09116. Claims 2, 3, and 19-25 are directed to encompass a method wherein the L1 element comprises a sequence at least about 95%, 98%, 99% similar to nucleotides 1-884 of SEQ ID NO:1, a region of the genome adjacent to a disease-associated marker and selecting any gene in the region containing an L1 element in an intronic region or in a 5' or 3' regulatory region as a candidate gene involved in SLE, and a sequence at least 95% similar to nucleotides 1-884 SEQ ID NO:1 wherein the distance between the first nucleotide of the L1 element and the first nucleotide of the gene is less than about 200,000 base pairs or 100,000 base pairs. A review of the full content of the specification indicates that the sequence of nucleotides of SEQ ID NO: 1 and all aforementioned variations, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

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With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a

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method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

It is furthermore noted that applicant(s) have listed a sequence which is known in the prior art and which has a high percentage sequence similarity to a claimed sequence. Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981 {1996}]; Wells

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et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)].

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (571)272-0748. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571)272-0747. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782. The official fax number is (703)872-9306.

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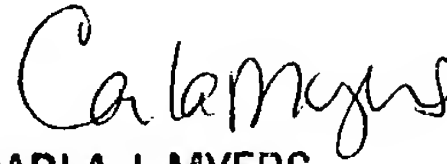
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Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (571)272-0518.

Sally Sakelaris



1/21/2004



CARLA J. MYERS
PRIMARY EXAMINER